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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,866	04/14/2004	Lawrence J. Stern	07917-212001 / UMMC 03-10	6194
26161	7590	11/29/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			JUNG, UNSU	
			ART UNIT	PAPER NUMBER
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DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/823,866	Applicant(s) STERN ET AL.	
	Examiner Unsu Jung	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-52 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-25, drawn to an array of MHC molecules complexed with antigen-derived peptides, classified in class 435, subclass 287.9, for example.
 - II. Claims 26-33, drawn to a method of identifying T cell epitope, classified in class 435, subclass 7.24, for example.
 - III. Claims 34-52, drawn to a method of making an array, classified in class 436, subclass 527, for example.
3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process. For example, the product of Group I can be used to isolate a population of T cells having a specific epitope.

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Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process. For example, the product of Group I can be made by a different immobilization method of using poly(ethylene glycol) coated surface.

Inventions II and III are independent and patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of Group II involves a step of contacting the array with a sample comprising T cells, which is not required by the method of Group III. The method of Group III involves a step of immobilizing MHC molecules complexed with antigen-derived peptides, which is not required by the method of Group II. Therefore, the methods of Groups II and III have different designs, modes of operation, and effects.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

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recognized divergent subject matter and searches for one group are not required by the others, restriction for examination purposes as indicated is proper.

Election of Species within Group I

6. This application contains claims directed to the following patentably distinct species of the claimed invention I. If Group I is elected, the Applicant is required to elect one species from each of the following three lists of species. For the species (indicated by letters) having subspecies (indicated by lower case Roman numerals) as listed below, the Applicant is further required to elect one subspecies.

List I: Substrate Coating (claim 8)

- a. Gold
- b. Biotin streptavidin
- c. Another molecule

List II: Immobilization

- a. Immobilization via MHC molecule (claims 9, 17, and 23)
 - i. Direct adsorption
 - ii. Peptide linkers
 - iii. Biotin-streptavidin
 - iv. Cysteine attachment
 - v. Amine attachment
 - vi. Metal chelate interaction
- b. Immobilization via antigen-derived peptide (claim 10, 18, and 24)
 - i. Direct adsorption
 - ii. Peptide linkers
 - iii. Biotin-streptavidin
 - iv. Cysteine attachment
 - v. Amine attachment
 - vi. Metal chelate interaction

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List III: Costimulatory Molecules

- a. Costimulatory antibodies (claims 12 and 13)
 - i. Anti-CD2
 - ii. Anti-CD11a
 - iii. Anti-CD28
 - iv. Anti-CD49d
 - v.
- b. Costimulatory agents (claims 12 and 14)
 - i. B7-1
 - ii. B7-2
 - iii. ICOSL
 - iv. B7-H1
 - v. B7-DC
 - vi. B7-H3
 - vii. B7-H4
 - viii. LFA-3
 - ix. ICAM-1
 - x. ICAM-2

List IV: Anti-Factor Antibodies (claim 20)

- a. Anti-IL-2
- b. Anti-IL-3
- c. Anti-IL-4
- d. Anti-IL-5
- e. Anti-IL-6
- f. Anti-IL-7
- g. Anti-IL-9
- h. Anti-IL-10
- i. Anti-IL-12
- j. Anti-IL-13
- k. Anti-IL-16
- l. Anti-IFN- γ
- m. Anti-TNF- α
- n. Anti-TNF- β
- o. Anti-GM-CSF
- p. Anti-OSM
- q. Anti-MIF
- r. Anti-TRAIL
- s. Anti-4-1BBL
- t. Anti-alpha-defensin

The Applicant is further advised that an election of species from List I must be consistent with an election of species from List II.

The species are independent or distinct because each species of substrate coating and immobilization linkers is chemically distinct and result in structurally distinct array of MHC molecules. Further, each species of costimulatory molecules is chemically distinct molecules having a different chemical composition and structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7, 11, 15, 16, 19, 21, 22, and 25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Election of Species within Group II

7. This application contains claims directed to the following patentably distinct species of the claimed invention II. If Group II is elected, the Applicant is required to elect one species from each of the following three lists of species. For the species (indicated by letters) having subspecies (indicated by lower case Roman numerals) as listed below, the Applicant is further required to elect one subspecies.

List I: Interaction Detection (claims 27-31)

a. Factor secretion (claims 27 and 30)

- i. IL-2
- ii. IL-3
- iii. IL-4
- iv. IL-5
- v. IL-6
- vi. IL-7
- vii. IL-9
- viii. IL-10
- ix. IL-12
- x. IL-13
- xi. IL-16
- xii. IFN- γ
- xiii. TNF- α
- xiv. TNF- β
- xv. GM-CSF
- xvi. OSM
- xvii. MIF
- xviii. TRAIL
- xix. 4-1BBL
- xx. α -defensin
- xxi. CD40L

b. Expression of activation marker (claims 27 and 29)

- i. CD3
- ii. CD4
- iii. CD8
- iv. CD11a
- v. CD25
- vi. CD27

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- vii. CD28
- viii. CD44
- ix. CD49e
- x. CD62L
- xi. CD69
- xii. CD71
- xiii. CD95
- xiv. CD152
- xv. Ly6A

- c. Intracellular signal (claims 27 and 28)
- d. CD30L (claim 31)
- e. CD27L (claim 31)
- f. FasL (claim 31)

List II: Anti-Factor Antibodies (claim 33)

- a. Anti-IL-2
- b. Anti-IL-3
- c. Anti-IL-4
- d. Anti-IL-5
- e. Anti-IL-6
- f. Anti-IL-7
- g. Anti-IL-9
- h. Anti-IL-10
- i. Anti-IL-12
- j. Anti-IL-13
- k. Anti-IL-16
- l. Anti-IFN- γ
- m. Anti-TNF- α
- n. Anti-TNF- β
- o. Anti-GM-CSF
- p. Anti-OSM
- q. Anti-MIF
- r. Anti-TRAIL
- s. Anti-4-1BBL
- t. Anti- α -defensin

The species are independent or distinct because each species of detecting interaction of a T cell with an MHC peptide complex requires a distinct step of detecting

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T cell activation or expression of a specific molecule. Further, each species of anti-factor antibodies is chemically distinct molecules having a different chemical composition and structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 26 and 32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election of Species within Group III

8. This application contains claims directed to the following patentably distinct species of the claimed invention III. If Group III is elected, the Applicant is required to elect one species from each of the following three lists of species. For the species

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(indicated by letters) having subspecies (indicated by lower case Roman numerals) as listed below, the Applicant is further required to elect one subspecies.

List I: Substrate Coating (claim 42)

- a. Gold
- b. Biotin streptavidin
- c. Another molecule

List II: Immobilization

- a. Immobilization via MHC molecule (claims 43)
 - i. Direct adsorption
 - ii. Peptide linkers
 - iii. Biotin-streptavidin
 - iv. Cysteine attachment
 - v. Amine attachment
 - vi. Metal chelate interaction
- b. Immobilization via antigen-derived peptide (claim 44)
 - i. Direct adsorption
 - ii. Peptide linkers
 - iii. Biotin-streptavidin
 - iv. Cysteine attachment
 - v. Amine attachment
 - vi. Metal chelate interaction

List III: Costimulatory Molecules

- a. Costimulatory antibodies (claims 46 and 47)
 - i. Anti-CD2
 - ii. Anti-CD11a
 - iii. Anti-CD28
 - iv. Anti-CD49d
- b. Costimulatory agents (claims 46 and 48)
 - i. B7-1
 - ii. B7-2
 - iii. ICOSL
 - iv. B7-H1
 - v. B7-DC

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- vi. B7-H3
- vii. B7-H4
- viii. LFA-3
- ix. ICAM-1
- x. ICAM-2

List IV: Anti-Factor Antibodies (claims 50 and 52)

- a. Anti-IL-2
- b. Anti-IL-3
- c. Anti-IL-4
- d. Anti-IL-5
- e. Anti-IL-6
- f. Anti-IL-7
- g. Anti-IL-9
- h. Anti-IL-10
- i. Anti-IL-12
- j. Anti-IL-13
- k. Anti-IL-16
- l. Anti-IFN- γ
- m. Anti-TNF- α
- n. Anti-TNF- β
- o. Anti-GM-CSF
- p. Anti-OSM
- q. Anti-MIF
- r. Anti-TRAIL
- s. Anti-4-1BBL
- t. Anti-alpha-defensin

The Applicant is further advised that an election of species from List I must be consistent with an election of species from List II.

The species are independent or distinct because each species of substrate coating and immobilization linkers is chemically distinct and result in structurally distinct array of MHC molecules. Further, each species of costimulatory molecules is chemically distinct molecules having a different chemical composition and structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 34-41, 45, 49, and 51 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Unsu Jung, Ph.D.
Patent Examiner
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11/24/06